REMARKS/ARGUMENTS

Reconsideration of this application is requested. Claims 1-20 will be pending in the application subsequent to entry of this Amendment.

Applicants' claims are directed to edible compositions containing at least 25 weight % of a pectin having a specified degree of esterification below 50% and at least 0.2% of a carotenoid and/or other active ingredient. These compositions are used to manufacture preparations in which the carotenoids are essentially not released in the intestinal tract but instead released in the colon as described in the present application at various passages including page 2, lines 19-24, page 3, lines 1-6, page 1, lines 11-15, page 5, lines 14-19 and especially page 4, lines 11-24. The above disclosures form the basis for new claim 20 which is directed to a method of delivering a carotenoid to the colon by administering the novel edible compositions. Claim 20 thus directed to subject matter disclosed in this application and applicants request that it be considered together with claims 1-19.

The issues raised in the outstanding Official Action relate to the patentability of all pending claims and particularly whether or not they are "obvious" over the disclosures of Jensen et al WO 91/06292 (acknowledged by applicants on page 2, second paragraph of the specification) taken in combination with U.S. 3,595,676 to Langen et al.

To establish a case of *prima facie* obviousness, all of the claim limitations must be taught or suggested by the prior art. *See* M.P.E.P. § 2143.03. A claimed invention is unpatentable if the differences between it and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art. *In re Kahn*, 78 USPQ2d 1329, 1334 (Fed. Cir. 2006) citing the legal standard provided in *Graham v. John Deere*, 148 USPQ 459 (1966). The *Graham* analysis needs to be made explicitly. *KSR v. Teleflex*, 82 USPQ2d 1385, 1396 (2007). It requires findings of fact and a rational basis for combining the prior art disclosures to produce the claimed invention. *See id.* ("Often, it will be necessary for a court to look to interrelated teachings of multiple patents . . . and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue"). The use of hindsight reasoning is impermissible. *See id.* at 1397 ("A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be

cautious of arguments reliant upon ex post reasoning"). Thus, a *prima facie* case of obviousness under Section 103(a) requires "some rationale, articulation, or reasoned basis to explain why the conclusion of obviousness is correct." *Kahn*, 78 USPQ2d at 1335; *see KSR*, 82 USPQ2d at 1396. A claim which is directed to a combination of prior art elements "is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *Id.* at 1396. Finally, a determination of *prima facie* obviousness requires a reasonable expectation of success. *See In re Rinehart*, 189 USPQ 143, 148 (C.C.P.A. 1976).

WO 91/06292 (Jensen et al) cites a "shopping" list of hydrocolloids in general (*see* page 4, line 35 to page 5, line 9). Only within this list it mentions explicitly "...; extracts from plants, such as pectin and arabinogalactan; ..." (page 4, line 38-39) and "...; chemically modified hydrocolloids, such as cellulose derivatives, including methyl cellulose, and other derivatives, including modified starches and low methoxyl pectin; ...". In all 13 examples neither pectin nor low methoxyl pectin was used (*see* the following table). Instead several kinds of gelatin, gum Arabic, cellulose ethers and modified food starch, either alone or in combination with sucrose were used.

hydrocolloid	example	citation
240 Bloom gelatine	1	page 8, line 12
	2	page 8, line 39
	3	page 9, line 25/26
	11	page 13, line 33/34
	12	page 14, line 15/16
low Bloom gelatine	4	page 10, line 5/6
70 Bloom gelatine	5	page 10, line 30
106 Bloom gelatine	6	page 11, line 17/18
	7	page 11, line 34/35
Gum arabic	8	page 12, line 11
Methocel E5 = water-soluble cellulose ethers (see enclosed information from the internet)	9	page 12, line 31
Capsul 50 = modified food starch	10	page 13, line 13
gelatine (different kinds) + sucrose	1	page 8, line 19;
	2	page 9, line 7;
	4	page 10, line 9/10
	5	page 10, line 37
	6	page 11, line 22/23
	7	page 11, line 39
	11	page 13, line 38
	12	page 14, line 20
	13	page 14, line 28/29
Gum Arabic + sucrose	8	page 12, line 16
Methocel E5 + sucrose	9	page 12, line 36
Capsul + sucrose	10	page 13, line 18

Thus, when reading Jensen et al the person skilled in the art would not be motivated to use pectin when other hydrocolloids are described as preferred (*see* examples and claim 10). The examiner is reminded that the claim directed to a combination of prior art elements is not proved

obvious merely by demonstrating that each of its elements was, independently, known in the prior art, as explained above.

Far afield from Jensen et al, U.S. 3,595,676 (Langen et al) deals with the manufacture of jams and jellies, thus it is concerned with a totally different technical field than the present invention. The only justification offered for combining the two references appears to be on page 4, second full paragraph, where it is argued that "a person having ordinary skill in the art at the time of applicants' invention (would have used) the pectin of Langen in the process and compositions of Jensen, since Langen teaches that low esterified pectin has an advantage over high esterified pectin in that it will not gel prematurely. Nowhere is it argued that a person skilled in the art concerned with making compositions such as microcapsules containing carotenoids (*see* Example 1 and claim 12) would seek to find a low esterified pectin as opposed to a high esterified pectin or any advantage that may flow from the use of one or the other.

In summary, the applied documents cannot be logically combined and to do so would be conjecture and/or hindsight reconstruction of the prior art and not based upon a fair and accurate assessment of information available to the skilled worker, information that the skilled worker would actually encounter and assimilate.

Claims 10, 11 and 14 are separately rejected based upon the combination of the two references discussed above taken in view of Cox U.S. 6,007,856. As these claims depend from one or more of the independent claims discussed above, these claims stand or fall with the claims from which they depend.

The claims depending from these independent claims are also not made obvious by the cited documents because the limitations of an independent claim are incorporated in their dependent claims. M.P.E.P. § 2143.03 citing *In re Fine*, 5 USPQ2d 1596 (Fed. Cir. 1988).

For the above reasons it is respectfully submitted that the claims of this application define inventive subject matter. Reconsideration and allowance are solicited.

Attention is directed to the concurrently filed Information Disclosure Statement and WO 99/20242 to Dubourdeaux et al.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: _____
Arthur R. Crawford
Reg. No. 25,327

ARC:eaw
901 North Glebe Road, 11th Floor
Arlington, VA 22203-1808
Telephone: (703) 816-4000
Facsimile: (703) 816-4100

http://www.dow.com/dowexcipients/products/methocel.htm

METHOCEL™ Products

METHOCEL™ Premium methylcellulose and hypromellose products are a broad range of water-soluble cellulose ethers. They enable pharmaceutical developers to create formulas for tablet coatings, granulation, controlled release, extrusion, molding, and for controlled viscosity in liquid formulations.

METHOCEL™ Premium Products for Pharmaceutical Applications

METHOCEL™ A15 Premium LV	Methylcellulose, USP	27.5 – 31.5	0	12 - 18
METHOCEL™ A4C Premium	Methylcellulose, USP			
METHOCEL™ A15C Premium	Methylcellulose, USP			
METHOCEL™ A4M Premium	Methylcellulose, USP			
METHOCEL™ E3 Premium LV	Hypromellose 2910	28 - 30	7 - 12	2.4 – 3.6
METHOCEL™ E5 Premium LV	Hypromellose 2910	28 - 30	7 - 12	4 - 6
METHOCEL™ E6 Premium LV	Hypromellose 2910	28 - 30	7 - 12	5 - 7
METHOCEL™ E15 Premium LV	Hypromellose 2910	28 - 30	7 - 12	12 - 18
METHOCEL™ E50 Premium LV	Hypromellose 2910	28 - 30	7 - 12	40 - 60
METHOCEL™ E4M Premium[2]	Hypromellose 2910	28 - 30	7 - 12	3000 - 5600
METHOCEL™ E10M Premium CR	Hypromellose 2910	28 - 30	7 - 12	7500 – 14,000
METHOCEL™ F50 Premium	Hypromellose 2906			
METHOCEL™ F4M Premium	Hypromellose 2906			
METHOCEL™ K3 Premium LV	Hypromellose 2208	19 - 24	7 - 12	2.4 – 3.6

METHOCEL™ K100 Premium LV[2]	Hypromellose 2208	19 - 24	7 - 12	80 – 120
METHOCEL™ K4M Premium[2]	Hypromellose 2208	19 - 24	7 - 12	3,000 – 5,600
METHOCEL™ K15M Premium[2]	Hypromellose 2208	19 - 24	7 - 12	11,250 – 21,000
METHOCEL™ K100M Premium[2]	Hypromellose 2208	19 - 24	7 - 12	80,000 – 120,000

[1]USP XXII

[2]Also available in faster hydrating CR (controlled release) grade